IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Verkaart et al. Appeal No.:

Serial No.: 09/623,793 Art Unit: 1743

Filed: September 8, 2000 Examiner: S. Siefke

For: APPARATUS FOR THE STERILE TRANSFER OF FLUIDS

AMENDED BRIEF ON APPEAL

This appeal is from the final rejection in the Office Action dated August 24, 2005, of claims 1, 3-10 and 15-19. A Notice of Appeal was timely filed on February 24, 2006.

TABLE OF CONTENTS

REAL PARTY IN INTEREST

The real party in interest in the application is Harvest Technologies Corporation, Suite 100, 40 Grissom Road, Plymouth, MA 02360. Assignments from the inventors or their representatives to Harvest Technologies Corporation was recorded in the United States Patent and Trademark Office on September 8, 2000, at reel 011141, frame 0325 and reel 011141, frame 0331, and on September 10, 2001, at reel 012337, frame 0428.

STATEMENT OF RELATED APPEALS AND INTERFERENCES

There are no prior or pending appeals, interferences or judicial proceedings known to appellant, assignee, or appellant's legal representatives that may be related to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1, 3-10 and 15-19, the claims on appeal, stand finally rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,997,811 (Esposito). Claims 2 and 11-14 were cancelled by amendments during the course of prosecution. The full text of the claims on appeal may be found in the Claims Appendix.

STATUS OF AMENDMENTS

No amendments were filed subsequent to the final rejection. All amendments have been entered.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 recites an apparatus for transferring a fluid to a sterile field. Specification, page 2, lines 16-17. The apparatus includes a casing (2) having a first part (4) and a second part (6). Specification, page 5, lines 8-10. The casing (2) is configured to receive a syringe containing the fluid and maintain sterility of the syringe when the first part (4) is connected to the second part (6). Specification, page 5, lines 7-12. The syringe may be removed from the casing (2) when the first part (4) is disconnected from the second part (6). Id. The first part (4) is adapted to receive a barrel portion (40) of the syringe and allow sterile, fluid communication with the syringe from a non-sterile field outside the casing (2). Specification, page 6, line 23 to page 7, line 3.

The second part (6) is adapted to receive a plunger portion (18) of the syringe. Specification, page 5, lines 13-14. The second part (6) is flexible in the direction of movement of the plunger (18) and configured to allow a user to engage and manipulate the plunger (18) when the syringe is in the casing (2) and the first (4) and second (6) parts are connected. Specification, page 5, lines 13-21. The first part (4) includes a connector (50) that detachably engages a tip (42) of the syringe and allows the fluid communication between the syringe and the exterior of the casing (2). Specification, page 8, lines 3-5. The first part (4) is readily detachable from the second part (6). Specification, page 5, lines 10-12.

Two embodiments of the second part are disclosed. In the embodiment shown in figure 1, the second part includes a bellows structure. In the second embodiment shown in figure 10, the bellows includes a flexible bag structure.

A preferred use for the invention is in the collection of fluids in a non-sterile field and transfer of such fluids to a sterile field. The invention finds particular utility in the collection of autologous blood products such as thrombin, cryoprecipitate and fibrinogen produced in the non-sterile field during surgery and transfer of these fluids to a sterile field.

Claim 3 depends from claim 1 and adds the limitation that the first part is a rigid tube as illustrated at reference numeral 4 and disclosed at page 3 beginning at line 3 and page 5 beginning at line 6.

Claim 4 depends from claim 1 and adds the limitation that the second part is a bellows as illustrated at 16 and disclosed at page 5 beginning at line 15.

Claim 5 depends from claim 1 and adds the limitation that the second part is a thin flexible sheet as shown at 68 in figures 10 and 11 and described at page 9 beginning at line 20.

Claim 6 depends from claim 5 and adds the limitation that the flexible sheet is in the form of a bag as illustrated in the drawings at 68.

Claim 7 depends from claim 1 and adds the limitation that the first part receives only a part of the barrel portion as shown, for example, in figure 8.

Claim 8 depends from claim 1 and recites means for releasable engagement of the plunger and a thumb knob 14. The means for releasable engagement is the clamp 12 disclosed at page 5 beginning at line 12 and connector 48 as shown in figure 8.

Claim 9 depends from claim 8 and recites the clamp 12.

Claim 10 depends from claim 8 and recites the connector 48.

Claim 15 depends from claim 1 and recites the lap connection between the casing and the syringe as disclosed at page 7.

Claim 16 depends from claim 1 and recites a Luer connection as shown at 44, 46 and described at page 7 beginning alt line 20.

Claim 17 depends from claim 1 and recites a Luer connector 50.

Claim 18 depends from claim 3 and recites gripping elements 22 described at page 6 lines 2-5.

Claim 19 depends from claim 5 and recites the feature wherein the flexible sheet 68 allows the user to grasp the syringe as disclosed at page 11.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellants seek review of the rejection of claims 1, 3-10 and 15-19 under 35 U.S.C. § 102(e) as anticipated by Esposito.

ARGUMENT

Introduction

The issue on appeal is whether the teachings of Esposito anticipate the invention recited in claims 1, 3-10 and 15-19. Because the Office Action wholly fails to establish a *prima facie* case of anticipation, the final rejection must be reversed and this application passed to issue.

The Esposito Patent

Esposito relates to a sterile syringe package and method for its use. Referring to Figure 1, a sterile syringe package 1 is shown having a sterile packaging 10 enclosing a sterile syringe 20. Sterile syringe packaging 10 is in the form of a pouch and includes sterile sheath 30 and a fitting member 50, which engages the syringe 20. The sterile sheath 30 has an opening portion 32 defined by a surrounding edge portion 34. Fitting member 50 is sealingly fixed with surrounding edge portion 34 of sheath 30 to form an enclosed syringe chamber 36 for housing sterile syringe 20. Fitting member 50 also is adapted to be removably connected to a connector luer 22 coupled to a syringe barrel 24 of sterile syringe 20.

Body portion 56 of fitting member 50 is adapted to be connected to surrounding edge portion 34 of sheath 30. When fitting member 50 is connected to sheath 30, first end 52 of fitting member 50 is located in syringe chamber 36 for connecting to connector 22 of syringe 20. Second end 54 of fitting member 50 is adapted to receive an injection device, such as a second syringe, for introducing a fluid into syringe 20.

In the embodiment shown in Figure 1, the Esposito sheath 30 includes a first sheet 38a and a second sheet 38b. These sheets are connected to each other at a sealing line 40, and they can be separated by peeling them apart such that they separate at the tear off portion 42. Thus, sterile sheath 30 is opened by peeling it open to allow the sterile syringe 20 to be delivered to a sterile environment.

In the second embodiment shown in figure 2, the sterile sheath is in the form of a tube having the tear-apart portion 42 at one end, providing a "peel-open type portion similar to that in the first preferred embodiment." (Col. 5, lines 14-18.)

Thus, Esposito discloses a sterile package wherein two thermoplastic layers are bonded together, as in figure 1, or a tube is formed of the thermoplastic material as in

figure 2. Both of these embodiments provide for a fitting member 50 that engages the tip of a syringe. The syringe is apparently removed from the package of figure 1 by first peeling the two layers 38a and 38b apart to expose the syringe and then by detaching the syringe from the member 50. The syringe is removed from the package of figure 2 by first opening the end of the tube to allow access to the syringe through that end and then removing the syringe in an fashion not described.

It appears from Esposito that the sheets 38a and 38b of the first embodiment remain connected to each other, at least by virtue of the connection to the fitting member 50, and that the tube of the second embodiment remains intact but for the removal of the tear-off portion 46.

The only disclosure of Esposito relating to the "operation" of the syringe is the introduction of a fluid into the sterile syringe 20 by injecting fluid from another syringe, not illustrated, that is attached to the fitting member 50. Esposito does not disclose any structure whereby an operator can operate the syringe from the exterior of the sterile package by grasping and manipulating the plunger of the syringe.

Esposito Does Not Anticipate Claims 1, 3, 7 and 15-17

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131; Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987). Esposito clearly fails to disclose, expressly or inherently, each and every element of claims 1, 3, 7 and 15-17, which may be considered to stand or fall together for the purposes of this appeal.

Claim 1 recites a casing having a first and a second part wherein the second part receives the plunger of a syringe, is flexible in the direction of movement of the plunger, and is configured to allow a user to engage and manipulate the plunger when the syringe is in the casing. Esposito has no disclosure of these features. Instead, Esposito discloses a sterile sheath made of a material that is disclosed only to be thermoplastic, which itself carries no implication of flexibility. Thermoplastic materials are those that become soft when heated but are not necessarily flexible.

Moreover, Esposito has no disclosure of a configuration that allows the plunger to be engaged by the user and manipulated when the syringe is in the casing. In fact,

Esposito's disclosure that the syringe is to be filled by injecting fluids through the member 50 from another syringe (col. 4, line 23; col. 5, lines 37-44) is evidence that the patent does not contemplate the manipulation of the plunger by a user. Injecting fluids through the member 50 does not involve engagement and manipulation of the plunger, and the examiner's assertions to the contrary are simply not supported by the reference.

Further, the reference in claim 1 of Esposito to "operation" of the syringe is nothing more than a reference to the injection of fluids from the second syringe and does not establish anticipation of claim 1 of the instant application by Esposito.

Esposito Does Not Anticipate Claim 4

Claim 4 adds to the recitation of claim 1 the limitation that the second part is a bellows, a feature nowhere explicitly disclosed by Esposito. The PTO simply states that the part 30 of Esposito "creates a bellow (*sic*) when the user applies pressure to the plunger to draw fluid into the syringe." It is clear from the Esposito disclosure that this is entirely incorrect. First, if the bellows were not already specifically formed in the sheath 30 it would not be possible to pull the plunger out in order to draw fluid into the syringe because the sterile sheath is not shown or disclosed to be extendable. Second, the clear disclosure that fluid is to be provided to the syringe by injecting it from another syringe, not by operation of the plunger by the user negates the Examiner's presumption.

The clear disclosure of Esposito is that the plunger can move within the package in response to the pressure applied by injecting fluid, but there is no disclosure of a user's ability to engage the plunger and manipulate it or any even remote suggestion of a bellows. Thus, Esposito does not disclose explicitly or implicitly the feature recited in claim 4.

Esposito Does Not Anticipate Claims 5, 6, and 19

Claim 5 adds to claim 1 the requirement that the second part is made of a thin flexible sheet, yet another feature that Esposito fails to disclose. As noted, Esposito merely states that his sheets are thermoplastic, which does not imply that they are necessarily thin or flexible. In accordance with the invention, the flexible nature of the second part as recited in claim 5 further defines how the second part of the invention is configured to allow the user to manipulate the plunger, and Esposito fails to disclose this feature.

Esposito Does Not Anticipate Claims 8-10

Claims 8-10 are directed to the feature whereby the user can engage the plunger through a thumb knob in releasable engagement with the plunger. Esposito simply has no disclosure whatsoever of this structure.

Esposito Does Not Anticipate Claim 18

Claim 18 recites the feature of the invention wherein the rigid tube of claim 3 includes gripping elements. These gripping elements correspond to elements 22[1], which are engaged by a user when manipulating the plunger, and Esposito simply shows no such structure.

In summary, applicants maintain that Esposito fails to disclose or suggest several features of the pending claims. Thus, the anticipation rejection cannot stand because "exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference." Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1574 (Fed. Cir. 1984). Because the Office Action fails to establish that Esposito anticipates claims 1, 3-10 and 15-19, applicants respectfully request that the rejection be reversed and this application passed to issue.

While it is noted that "gripping elements" 24 and 26 are also disclosed, those are attached to the second part. The only disclosed gripping elements attached to the first part are the finger grips 22.

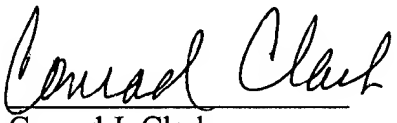
CONCLUSION

Because the final rejection is in error, applicants respectfully request that the Honorable Board of Patent Appeals and Interferences reverse the rejections made in the Office Action and find claims 1, 3-10 and 15-19 allowable.

Applicants submit that this Appeal Brief is being timely filed and meets the requirements set forth under 35 U.S.C. § 134 and in 37 C.F.R. § 41.37.

All necessary extensions of time are requested. Please charge any fee deficiency or credit any excess to Deposit Account 50-1088.

Respectfully submitted,
CLARK & BRODY



Conrad J. Clark
Reg. No. 30,340

Suite 250
1090 Vermont Ave., NW
Washington, D.C. 20005
202-835-1111
202-835-1755(fax)
June 29, 2007

CLAIMS APPENDIX

1. Apparatus for transferring a fluid to a sterile field comprising a casing having a first part and a second part, wherein said casing is configured to receive a syringe containing said fluid and maintain sterility of said syringe when said first part is connected to said second part, said syringe may be removed from said casing when said first part is disconnected from said second part, said first part is adapted to receive a barrel portion of said syringe and allow sterile, fluid communication with said syringe from a non-sterile field outside said casing, said second part is adapted to receive a plunger portion of said syringe, and said second part is flexible in the direction of movement of said plunger and configured to allow a user to engage and manipulate said plunger when said syringe is in said casing and said first and second parts are connected, wherein said first part includes a connector that detachably engages a tip of said syringe and allows said fluid communication between said syringe and the exterior of said casing, and said first part is readily detachable from said second part.

2. (Cancelled)

3. Apparatus according to claim 1 wherein said first part is a rigid tube.

4. Apparatus according to claim 1 wherein said second part is a bellows.

5. Apparatus according to claim 1 wherein said second part is made of a thin flexible sheet.

6. Apparatus according to claim 5 wherein said thin flexible sheet is in the shape of a bag.

7. Apparatus according to claim 1 wherein said first part is adapted to receive only part of said barrel portion and said second part is adapted to receive said plunger portion and a part of said barrel portion.

8. Apparatus according to claim 1 wherein said second part comprises means for releasable engagement of said plunger and a thumb knob that can be engaged by a user's thumb.

9. Apparatus according to claim 8 wherein said means for releasable engagement comprises a clamp.

10. Apparatus according to claim 8 wherein said means for releasable engagement comprises a disc with a slot for receiving an end of said plunger.

11. (Cancelled)

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

15. Apparatus according to claim 1 wherein said connector provides a lap joint between said casing and said syringe inlet.

16. Apparatus according to claim 1 wherein said connector provides a Luer connector between said casing and said syringe inlet.

17. Apparatus according to claim 1 wherein said connector provides a Luer connector on the exterior of said casing for engaging a needle located in the non-sterile field.

18. Apparatus according to claim 3 wherein said rigid tube includes gripping elements.

19. Apparatus according to claim 5 wherein said flexible sheet allows a user to grasp said syringe through said flexible sheet.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.

UNITED STATES PATENT AND TRADEMARK OFFICE

UN
Un
Adc

Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,793	09/08/2000	Wesley H Verkaart	70869-0068US	6666

22902 7590 05/30/2007

CLARK & BRODY
1090 VERMONT AVENUE, NW
SUITE 250
WASHINGTON, DC 20005

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED: 05/30/2007

COPY

Please find below and/or attached an Office communication concerning this application or proceeding.

Notification of Non-Compliant Appeal Brief (37 CFR 41.37)	Application No. 09/623,793	Applicant(s) VERKAART ET AL.	
	Examiner Samuel P. Siefke	Art Unit 1743	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The Appeal Brief filed on *8/24/06* is defective for failure to comply with one or more provisions of 37 CFR 41.37.

To avoid dismissal of the appeal, applicant must file anamended brief or other appropriate correction (see MPEP 1205.03) within **ONE MONTH or THIRTY DAYS** from the mailing date of this Notification, whichever is longer. **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136.**

1. ☐ The brief does not contain the items required under 37 CFR 41.37(c), or the items are not under the proper heading or in the proper order.

2. ☐ The brief does not contain a statement of the status of all claims, (e.g., rejected, allowed, withdrawn, objected to, canceled), or does not identify the appealed claims (37 CFR 41.37(c)(1)(iii)).

3. ☐ At least one amendment has been filed subsequent to the final rejection, and the brief does not contain a statement of the status of each such amendment (37 CFR 41.37(c)(1)(iv)).

4. ☒ (a) The brief does not contain a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number and to the drawings, if any, by reference characters; and/or (b) the brief fails to: (1) identify, for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function and step plus function under 35 U.S.C. 112, sixth paragraph, and/or (2) set forth the structure, material, or acts described in the specification as corresponding to each claimed function with reference to the specification by page and line number, and to the drawings, if any, by reference characters (37 CFR 41.37(c)(1)(v)).

5. ☐ The brief does not contain a concise statement of each ground of rejection presented for review (37 CFR 41.37(c)(1)(vi))

6. ☐ The brief does not present an argument under a separate heading for each ground of rejection on appeal (37 CFR 41.37(c)(1)(vii)).

7. ☐ The brief does not contain a correct copy of the appealed claims as an appendix thereto (37 CFR 41.37(c)(1)(viii)).

8. ☐ The brief does not contain copies of the evidence submitted under 37 CFR 1.130, 1.131, or 1.132 or of any other evidence entered by the examiner **and relied upon by appellant in the appeal**, along with a statement setting forth where in the record that evidence was entered by the examiner, as an appendix thereto (37 CFR 41.37(c)(1)(ix)).

9. ☐ The brief does not contain copies of the decisions rendered by a court or the Board in the proceeding identified in the Related Appeals and Interferences section of the brief as an appendix thereto (37 CFR 41.37(c)(1)(x)).

10. ☒ Other (including any explanation in support of the above items):

The dependent claims 4, 5, 6, 8-10, 18 and 19 are not mapped properly in the "Summary of the claimed subject matter" as described in 4a above.

Jill Warden
Supervisory Patent Examiner
Technology Center 1700